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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,546	07/08/2003	Chris Miller	0-03-046	9069

34492 7590 11/03/2005

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,546

Applicant(s)

MILLER ET AL.

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 9-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 9-15, 17-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/8/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Applicant's arguments with respect to claims 9-15,17-26 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-15,17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenzler on record in view of Cantwell (US 6000403; 12/14/99). Stenzler teaches a method of promoting healing of a wound comprising topically applying to the damaged tissue (wound) which is surrounded by an air impermeable cover (bathing unit) an effective amount of gaseous nitric oxide (wound healing agent), oxygen (wound healing agent) and nitrogen (inert agent that enhances local amount nitric oxide delivered to wound). The nitric oxide is applied from a pressurized cylinder which suggests a spray application method. Stenzler teaches that nitrogen prevents the nitric oxide from converting to NO₂. See abstract, column 4 lines 1-47. The method promotes the healing of infections incurred by bacteria (pathological process). See column 3 lines 17-25. Stenzler employs a nitric oxide concentration ranging from about 100 to around 1200 ppm in the method. See column 3 line 46 – column 4 line 24. Stenzler teaches the exposure of wound to nitric oxide for an average of 8 hours. See column 2 lines 7-22. Stenzler does not teach a method of employing 20-1000 ppm gaseous nitric acid.

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Stenzler does not disclose that oxygen is a wound healing agent. However, Cantwell discloses that oxygen is wound healing agent. See abstract, column 2 lines 20-29, column 5 lines 39-50. Therefore, the oxygen in Hole functions as a wound healing agent. Stenzler's method does disclose a step wherein the wound is pretreated or posttreated with nitric oxide plus an agent. In essence both Applicant and Stenzler teaches a step involving topically applying gaseous nitric oxide plus an agent to a wound. Stenzler does not teach that the application of gaseous nitric oxide plus agent is prior to or after exposing the wound to nitric oxide. However, in the absence of unexpected results, it is obvious that both inventions would yield similar results since both prior art and instant inventions teach the step of applying gaseous nitric oxide plus an agent to the wound. Applicant has not demonstrated the criticality of the pretreatment or post-treatment of the wound with nitric oxide plus agent. It would have been obvious to one having ordinary skill in the art to employ the instant ppm amount of gaseous nitric acid since the prior art and instant invention ppm amounts of gaseous nitric overlap. With respect to the time of exposure, one having ordinary skill in the art would have determined the optimum exposure time. One would have been motivated to do this in order to promote effective wound healing.

Claims 9-15,17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hole on record in view of Cantwell (US 6000403; 12/14/99). Hole teaches a method of promoting healing of a wound comprising topically applying to the damaged tissue (wound) which is surrounded by an air impermeable cover (envelope) an effective amount of gaseous nitric oxide (wound healing agent), oxygen (wound healing agent)

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and nitrogen (inert agent that enhances local amount nitric oxide delivered to wound).

The nitric oxide is applied from a pressurized cylinder which suggests a spray application method. Hole teaches that nitrogen prevents the nitric oxide from converting to NO₂. See abstract, paragraph 36. The method promotes the healing of infections incurred by bacteria (pathological process). See paragraph 9. Hole employs a nitric oxide concentration ranging from about 100 to around 1000 ppm in the method. See paragraphs 42-43. Hole teaches the exposure of wound to nitric oxide for an average of 8 hours. See paragraph 10. Hole does not disclose that oxygen is a wound healing agent. However, Cantwell discloses that oxygen is wound healing agent. See abstract, column 2 lines 20-29, column 5 lines 39-50. Therefore, the oxygen in Hole functions as a wound healing agent. Hole does not teach a method employing 20-1000 ppm gaseous nitric acid. Hole's method does not disclose a step wherein the wound is pretreated or posttreated with nitric oxide plus a wound healing agent prior to nitric oxide treatment. In essence both Applicant and Hole teaches a step involving topically applying gaseous nitric oxide plus an agent to a wound. Hole does not teach that the application of gaseous nitric oxide plus agent is prior to or after exposing the wound to gaseous nitric oxide. Applicant has not demonstrated the criticality of the pretreatment or post-treatment of the wound with nitric oxide plus agent. Applicant has not demonstrated the criticality of the pretreatment or post-treatment of the wound with nitric oxide plus agent. It would have been obvious to one having ordinary skill in the art to employ the instant ppm amount of gaseous nitric acid since the prior art and instant invention ppm amounts of gaseous nitric overlap.

Applicant's Argument

I. Applicant argues that office action, without any support, states that Hole's or Stenzler's method does disclose a step wherein the wound is pretreated or posttreated with nitric oxide gas plus an agent. Applicant is correct. Examiner intended to state that Stenzler's method does not disclose a step wherein the wound is pretreated or posttreated with nitric oxide gas plus an agent. This matter is addressed in the action cited above.

Applicant argues that prior art does not teach administration of nitric oxide to tissue flap and surrounding area to promote flap viability. Examiner argues that prior art teaches application of nitric oxide and oxygen to the wound as a whole. Therefore, said application would encompass the flap of the wound.

Applicant argues that a "pressurized cylinder" does not necessarily indicate a "spray application method". Examiner argues that a "pressurized cylinder" encompasses a "spray application method". For this reason, a "pressurized cylinder" suggests a "spray application method".

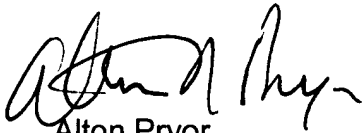
Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton Pryor', is written over the printed name.

Alton Pryor
Primary Examiner
AU 1616